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# The Rise and Fall of the MMR Litigation: A Comparative Perspective

## The Rise and Fall of the MMR Litigation

### I. INTRODUCTION

Autism is the term used to describe ‘a complex and severe set of developmental disorders characterised by sustained impairments in social interaction, impairments in verbal and nonverbal communication, and stereotypically restricted or repetitive patterns of behaviours and interests’.<sup>1</sup> Over the last 15 years, stories surrounding the challenging condition of autism have never been far from the headlines. Many parents who have autistic children continue to search for a possible cause. When, in 1998, Andrew Wakefield and his colleagues hypothesised that there could be an association between the Measles, Mumps, Rubella (MMR) vaccine and autism, several though not all parents of autistic children became partially or totally convinced that this was the answer.<sup>2</sup> As a consequence, many parents in the UK took to seeking legal advice as to whether they could proceed in a legal action against the manufacturers of the vaccine. In the US, these proceedings were brought against the Secretary for Health and Human services under the National Childhood Vaccine Compensation Program.

This chapter seeks to assess the significance of the rise and fall of this litigation in the US and UK. The importance of the 1998 Wakefield study to the fuelling of such litigation is explained, as well as the reasons for its collapse pre-trial in the UK. It then examines the value of the relevant scientific evidence exposed in six test cases of the Omnibus Autism Proceeding (OAP) under the National Childhood Vaccine Injury Act of 1986 (NVIA), decided in February 2009 and March 2010. These cases essentially explored two causation theories, viz that MMR vaccines and thimerosal-containing vaccines could combine to cause autism, and that thimerosal vaccines alone can cause autism. The legal implications of these complex and lengthy judgments are explored. The position in the United States is contrasted with the much more liberal approach to causation established in France by the Cour de Cassation for medicinal product liability cases in the context of injury allegedly caused by the Hepatitis B vaccine through the use of presumptions of causation.

Finally, a discussion of the outcome of the General Medical Council Hearing on Dr Wakefield and his two co-authors of the 1998 study is provided. The paper

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\* I am grateful to the General Medical Council for permission to use the Transcripts of the hearings of the Fitness to Practise Panel (Misconduct) in the case of Wakefield, Walker-Smith and Murch, 16 July 2007 to 24 May 2010 in the writing of this chapter.

<sup>1</sup> Institute of Medicine, *Immunization Safety Review: Vaccines and Autism* (Washington DC, The National Academies Press, 2004), Executive Summary, p 3.

<sup>2</sup> See especially, D Goldberg, ‘MMR, autism, and Adam’ (2000) 320 *British Medical Journal* 389. (In this Personal View for the *British Medical Journal*, Professor David Goldberg, a consultant clinical epidemiologist and Honorary Professor of Public Health at the University of Glasgow, wrote about his then 10-year-old son who is severely autistic, commenting that, by virtue of his NHS and public health affiliations, he was ‘tarred with the establishment brush’ by some parents of other autistic children for failing to join the ‘Wakefield bandwagon’).

concludes with some lessons to be learned from this litigation, both in the UK and in France in the light of its liberal approach.

## II. BACKGROUND: THE VACCINES AND AUTISM CONTROVERSY

### The Vaccines and Autism Controversy

The hypothesis that the receipt of the MMR vaccine was linked to the development of autism spectrum disorders and gastrointestinal problems in children principally emerged from the notorious (now retracted) paper by Andrew Wakefield, then of the Royal Free Hospital in London, John Walker-Smith and 11 other colleagues from the same institution.<sup>3</sup> This paper was published in *The Lancet* on 28 February 1998, and it reported on 12 children with chronic enterocolitis and regressive developmental disorder. Until its retraction on 6 February 2010,<sup>4</sup> it was this publication that provided the basis for litigation both in the UK and US and generated ‘a decade long public health scare,’<sup>5</sup> which has led to hundreds of thousands of children in the UK being unprotected.<sup>6</sup> The paper noted that the ‘onset of behavioural symptoms was associated by the parents with measles, mumps, and rubella vaccination in eight of the 12 children’, and that in eight children, ‘the average interval from exposure to first behavioural symptoms was 6.3 days (range 1–14)’.<sup>7</sup> Over the ensuing decade, the epidemiological evidence has consistently shown no causal link between MMR vaccine and autism and inflammatory bowel disease.<sup>8</sup>

## III. UK MMR LITIGATION

### A. Legal Aid Funding and Establishment of Group Litigation

By far the majority of claims against the manufacturers of the MMR vaccine were initially funded by the Legal Aid Board in England and Wales (which became the Legal Services Commission).<sup>9</sup> This body was responsible for providing legal aid for

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<sup>3</sup> AJ Wakefield, et al, ‘Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children’ [retracted] (1998) 351 *Lancet* 637–41); The Editors of *The Lancet*, ‘Retraction-Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children’ (2010) 375 *Lancet* 445.

<sup>4</sup> The Editors of *The Lancet*, ‘Retraction-Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children’ (2010) 375 *Lancet* 445.

<sup>5</sup> B Deer, ‘How the Case Against the MMR Vaccine Was Fixed’ (2011) 342 *British Medical Journal* 77.

<sup>6</sup> F Godlee, J Smith and H Marcovitch, Editorial, ‘Wakefield’s article linking MMR vaccine and autism was fraudulent’ (2011) 342 *British Medical Journal* 64, 65.

<sup>7</sup> AJ Wakefield, et al, ‘Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children’ [retracted] (1998) 351 *Lancet* 637, 638.

<sup>8</sup> See below, n 53.

<sup>9</sup> Access to Justice Act 1999, s 1. Repealed by Legal Aid, Sentencing and Punishment of Offenders Act 2012, [Sch 5\(1\) para 51\(a\)](#) (1 April 2013 subject to saving and transitional provisions as specified in SI 2013/534, regs 6–13). The Legal Services Commission was abolished by the Legal Aid, Sentencing and Punishment of Offenders Act 2012, s 38. An Executive Agency within the Ministry of Justice (the Legal Aid Agency) has been created within the Ministry of Justice to administer legal aid.

Multi-Party Actions, providing that the individuals satisfied a financial means test and that the case met a legal merits test, which required cases to have a reasonable prospect of success, and for the costs of the action to be reasonable, compared to the potential damages.<sup>10</sup> Consequent upon representations in the form of a proposed protocol and costing proposals by Richard Barr (a solicitor in England, who had public funding in relation to the pursuit of litigation against manufacturers of the MMR vaccine, viz GlaxoSmithKline, Aventis Pasteur and Merck) the Legal Aid Board authorised funding of £50,000 in two instalments of £25,000, in late 1996 and 1999 respectively, for Wakefield to investigate a potential link between MMR and autism in respect of 10 named children.<sup>11</sup> This money was paid into a numbered hospital charity account which was held by the Special Trustees of the Royal Free Hampstead NHS Trust, and then paid out for research by Wakefield on the MMR vaccine in the medical school.<sup>12</sup> At least four of the eventual 12 children included in the *Lancet* Study were involved in the investigations which were covered by Legal Aid funding.

As a result of a confidential report to the Legal Aid Board in January 1999,<sup>13</sup> one month later the Legal Aid Board awarded £800,000 to Unigenetics, a company incorporated with Wakefield and a Dublin pathologist, John O’Leary as directors, to perform polymerase chain reaction tests on the bowel tissue and blood samples of children in order to provide evidence of the alleged vaccine-derived measles virus.<sup>14</sup> A Practice Direction of 8 July 1999, promulgated by the then Lord Chief Justice of England and Wales, resulted in all claims for damage alleged to have arisen out of the inoculation with the MMR/MR vaccines being given the status of, and being dealt with under the umbrella of, Group Litigation.<sup>15</sup>

## B. Withdrawal of Funding and Dissolution of Group Litigation

However, in December 1999, in the light of increasing concerns about a potentially serious conflict of interest between Wakefield’s academic employment by University

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<sup>10</sup> The Legal Services Commission (LSC) Funding Code set out the criteria according to which cases could be funded, in accordance with the Access to Justice Act 1999, s 8 (repealed by Legal Aid, Sentencing and Punishment of Offenders Act 2012, [Sch 5\(1\) para 51\(a\)](#)). The criteria were laid down in Part 1 of the Code. The criteria for Multi-Party Actions (MPAs) are described in the *Legal Services Commission Manual*, vol 3, Part C, ch 15. See also the *Legal Services Commission Manual*, vol 3, Part C, ch 4, Merits, Costs and Damages. From 1 April 2013, civil legal services provided in relation to personal injury or death are exempted from legal aid: Legal Aid, Sentencing and Punishment of Offenders Act 2012, Sch 1, Part 2. Personal injury claims against pharmaceutical companies will no longer be eligible for legal aid.

<sup>11</sup> General Medical Council, Fitness to Practise Panel (Misconduct), Day 11, 30 July 2007, Transcript, 11-4C–11-17H, 11-26B–E. For discussion of the history of the anti-MMR campaign, including Mr Barr’s involvement, see M Fitzpatrick, *MMR and Autism: What Parents Need to Know* (London and New York, Routledge, 2004) 101–17.

<sup>12</sup> General Medical Council, Fitness to Practise Panel Hearing, 28 January 2010, p 6. It subsequently transpired that Wakefield had failed to inform either his colleagues at the Royal Free, or the editor of *The Lancet*, about his involvement in the MMR litigation and his personal interest in establishing the autism link: see below, V.A.

<sup>13</sup> AJ Wakefield, ‘Developmental disorders in children and measles, mumps, rubella (MMR) vaccine, Interim Report to the Legal Aid Board’, January 1999, cited in B Deer, ‘How the Vaccine Crisis was Meant to Make Money’ (2011) 342 *British Medical Journal* 136, 142, fn 24.

<sup>14</sup> B Deer, ‘How the Vaccine Crisis was Meant to Make Money’ (2011) 342 *British Medical Journal* 136, 140.

<sup>15</sup> Practice Direction: MMR/MR Vaccine Litigation, 8 July 1999.

College London (UCL),<sup>16</sup> and his involvement in a company to develop products based on his MMR claims, the provost of UCL demanded that Wakefield confirm or refute the possible causal relationships between MMR and autism/autistic enterocolitis/inflammatory bowel disease.<sup>17</sup> The study never transpired, as the original study had been fraudulent and it would have been impossible to replicate it with greater numbers. Wakefield then left UCL.<sup>18</sup> Over the next few years a series of epidemiological studies were published which repeatedly found no evidence of a causal link between the MMR vaccine and autism or bowel disorder. Accordingly, following counsel for the claimants' submission of a report to the Legal Services Commission that they were unable to establish a case that MMR causes autism or bowel disease, on 29 September 2003 the Legal Services Commission decided to cease all funding for cases related to autism and bowel disease on the grounds that the litigation had no reasonable prospect of success. The decision was supported on 30 September 2003 by the Funding Review Committee (FRC), an independent appeal body chaired by a Queen's Counsel and three expert solicitors. The High Court rejected an application for a judicial review of the decision on 27 February 2004.<sup>19</sup> 37 individual appeals were then heard by the FRC, which upheld the LSC's decision to cease all funding for cases related to autism and bowel disease on 15 October 2004.<sup>20</sup> With only two claimants continuing with claims (those two having had their public funding restored, the rest having had their funding withdrawn by the Legal Services Commission), and there being no realistic prospect of any new claims being progressed in the light of the unavailability of public funding, the status of the litigation as group litigation was dissolved in June 2007.<sup>21</sup> It was stressed, however, that the claims were not being allowed to proceed not because the court believed that the claims had no merit (which had never been addressed by the court), but because it was not practicable for the claims to go ahead without public funding.<sup>22</sup>

## IV. THE US OMNIBUS AUTISM PROCEEDING TEST CASES

### The US Omnibus Autism Proceeding

#### A. The Omnibus Autism Proceeding (OAP)

Just as the UK MMR litigation was grinding to a halt in 2007, the United States were about to commence three test cases in the Omnibus Autism Proceeding (OAP) under the National Childhood Vaccine Injury Act of 1986 (NVIA). The OAP is a

<sup>16</sup> The Royal Free and University College Medical Schools had now merged.

<sup>17</sup> B Deer, 'How the Vaccine Crisis was Meant to Make Money (2011) 342 *British Medical Journal* 136, 142.

<sup>18</sup> *ibid.*

<sup>19</sup> 'Parents refused aid to fight MMR', 27 February 2004, available at: [news.bbc.co.uk/1/hi/health/3494360.stm](http://news.bbc.co.uk/1/hi/health/3494360.stm).

<sup>20</sup> Press Release, MMR Appeals, 15 October 2004, available at: [www.legalservices.gov.uk/press/press\\_release31.asp](http://www.legalservices.gov.uk/press/press_release31.asp); C Dyer, 'Parents claiming a link between MMR vaccine and autism lose final appeal for legal aid' (2004) 329 *British Medical Journal* 939.

<sup>21</sup> See *Re MMR and MR Vaccine Litigation; Sayers and others v Smithkline Beecham plc and others* [2007] EWHC 1335, QB, [2007] All ER (D) 67 (Jun), [35], [37].

<sup>22</sup> *ibid* [37], Keith J.

coordinated proceeding, established in July 2002 and devised as a means by which 5,000 cases filed with the National Childhood Vaccine Injury Compensation Program – in which it has been alleged that autism or a similar disorder was caused by one or more vaccines – could be handled by the program in a timely and effective manner.<sup>23</sup> The Office of Special Masters of the US Court of Federal Claims did this by dividing the claims into several theories of causation, and allocating three test cases for each theory. Shortly before the first test case, *Cedillo*, was due to begin, the US Secretary of Health and Human Services was granted permission to obtain from the records of the English High Court, copies of expert witness reports filed by the defendants in the UK MMR/MR Vaccine Litigation, so as to use these documents in the Omnibus Autism Proceedings in the US.<sup>24</sup>

While the court cases in the UK were brought against the three manufacturers of the MMR vaccine, GlaxoSmithKline, Aventis Pasteur and Merck, cases under the National Childhood Vaccine Injury Compensation Program are brought against the Secretary for Health and Human Services. Unlike in the UK, where proceedings never reached the trial stage, in the US there has been an exhaustive analysis of the scientific and legal evidence by the Special Masters of the Court of Federal Claims. In the context of the US MMR Litigation, the assessment of the value of the scientific evidence came to prominence in the first three test cases of the OAP under the NVIA, which were decided in February 2009, as well as a further three test cases in March 2010. A group of counsel selected from attorneys representing petitioners in the autism cases, known as the Petitioners' Steering Committee (PSC) – which was established in 2002 to obtain and present evidence on the general issue of whether certain vaccines could cause autism and, if so, in what circumstances<sup>25</sup> – presented two different theories of 'general causation' in the OAP, designating three 'test cases' for each of the two theories. The long-awaited test cases in these proceedings are of considerable importance, since they have irrefutably rejected the petitioners' first and second general causation theories. The Special Masters in these proceedings, having considered all the available scientific evidence, concluded in the first three test cases that there was no merit in the petitioners' first general causation theory that MMR vaccines and thimerosal-containing vaccines could combine to cause autism, and concluded in the second three test cases that there was no merit in the petitioners' second causation theory that thimerosal vaccines alone can cause autism. The proceedings in these six test cases are concluded, and those petitioners remaining in the OAP must now decide whether to pursue their cases by submitting new evidence on causation, or take other action to exit the Program.<sup>26</sup> Other theories of causation are being advanced in individual cases, but there are no new test cases planned.<sup>27</sup>

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<sup>23</sup> The OAP was established by the Chief Special Master of the US Court of Federal Claims: see Autism General Order # 1 2002 WL31696785, 2002 US Claims LEXIS 365 (Fed Cl Spec Mstr July 3, 2002).

<sup>24</sup> *Sayers v Smithkline Beecham Plc, Smith Kline & French Laboratories Ltd, Merck & Co Inc, Sanofi Pasteur MSD Ltd* [2007] EWHC 1346, QB.

<sup>25</sup> The PSC has now disbanded, and the remaining cases will be resolved on a firm-by-firm or individual basis, without PSC input or participation: *In Re: Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder, Various Petitioners v Secretary of Health and Human Services*, Autism Update, January 12, 2011, 2.

<sup>26</sup> *ibid* 3.

<sup>27</sup> *ibid* 4.



## B. The First Three Test Cases and the Petitioners' First Theory

### (i). The First Three Test Cases

The United States Vaccine Court Omnibus Autism Proceeding under the NVIA gave three rulings in the three test cases where the petitioners claimed that measles-mumps-rubella vaccines combined with thimerosal-containing vaccines administered to three children had caused several conditions, including autism<sup>28</sup> and chronic gastrointestinal symptoms. The key question under the National Vaccine Injury Compensation Program is the establishment of a causal link between the vaccination and the injury. In some cases the petitioner may simply demonstrate the occurrence of a so-called Table Injury, ie that the vaccine recipient was administered a vaccine and suffered an injury covered by the NVIA, occurring within an applicable time period following the vaccination specified in the Vaccine Injury Table.<sup>29</sup> If so, the Table Injury is presumed to have been caused by the vaccination.<sup>30</sup> However, in the Omnibus Autism Proceeding, each of the petitioners' test cases was based on an exception to the Table. Here, the petitioners claimed that they suffered injuries not of the type covered in the Table, but that they could show by a preponderance of evidence that their injuries were 'caused-in-fact' by the vaccination in question.<sup>31</sup> This is known as an *off-Table injury* or *causation-in-fact claim*. In contrast to the relaxation of the burden of proving causation for injuries satisfying the Table, the burden of proof on the petitioner in a causation-in-fact claim is a heavy one.<sup>32</sup>

Essentially, the three test cases, *Cedillo*,<sup>33</sup> *Snyder*<sup>34</sup> and *Hazlehurst*,<sup>35</sup> were three of more than 5,000 cases filed with the National Vaccine Injury Compensation Program, in which it has been alleged that autism or a similar disorder was caused by one or more vaccines. The evidentiary record was described by the Special Master in

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<sup>28</sup> In the Omnibus Proceeding, it was noted that the terms 'autism', 'autistic' and 'autism spectrum disorder' would interchangeably be used to refer to the entire group of disorders within the category of 'pervasive developmental disorder' (PDD).

<sup>29</sup> 42 USC § 300aa-11(c)(1)(C)(i).

<sup>30</sup> 42 USC § 300aa-11(c)(1)(C)(i); § 300aa-13(a)(1)(A).

<sup>31</sup> 42 USC § 300aa-11(c)(1)(C)(ii)(I); § 300aa-13(a)(1)(A); *Moberly v Secretary of Health & Human Services* 592 F 3d 1315, 1322 (Fed Cir 2010); *Shyface v Secretary of Health & Human Services* 165 F 3d 1344, 1352–53 (Fed Cir 1999); *Hines v Secretary of Health & Human Services* 940 F 2d 1518, 1525 (Fed Cir 1991).

<sup>32</sup> *Grant v Secretary of Dept of Health & Human Services* 956 F 2d 1144, 1148 (Fed Cir 1992); *Hodges v Secretary of Dept of Health & Human Services* 9 F 3d 958, 961 (Fed Cir 1993). Nonetheless, it has been judicially observed that Congress 'clearly intended' that its goal of rendering expeditious, certain and generous determinations should apply equally to Table and off-Table claims: *Stevens v Secretary of HHS*, No 99-594 V, 2001 WL 387418 (Fed CI Mar 30, 2001) at \*7, Chief Special Master Golkiewicz (noting the difficulties associated with causation in fact cases under the National Childhood Vaccine Injury Compensation Program); HR Rep No 99-908, 13; see further, KE Strong, Note, 'Proving Causation Under the Vaccine Injury Act: A New Approach for a New Day' (2007) 75 *George Washington Law Review* 426, 442–46 (submitting that the medical and scientific uncertainties surrounding vaccine injuries, as well as the lack of a uniform standard for causation in fact cases, has meant that the goals of Congress have not been met for petitioners who require to prove off-Table claims).

<sup>33</sup> *Cedillo v Secretary of Health & Human Services*, 98-916V, 2009 WL 331968 (Fed CI Feb 12, 2009), aff'd, 89 Fed CI 158, 164, 184 (2009), aff'd, 617 F 3d 1328, 1334, 1349–50 (Fed Cir 2010).

<sup>34</sup> *Snyder v Secretary of Health & Human Services*, 01-162V, 2009 WL 332044 (Fed CI Feb 12, 2009), aff'd, 88 Fed CI 706, 708, 748 (2009).

<sup>35</sup> *Hazlehurst v Secretary of Health & Human Services*, 03-654V, 2009 WL 332306 (Fed CI Feb 12, 2009), aff'd, 88 Fed CI 473, 475, 490 (2009), aff'd, 604 F 3d 1343, 1345, 1354 (Fed Cir 2010).

*Cedillo* as ‘massive’,<sup>36</sup> and one which dwarfed, by far, any evidentiary record in any Program case. The amount of medical literature filed in records of the three cases was noted as being ‘staggering’.<sup>37</sup> During the evidentiary hearings, a total of 28 expert witnesses testified. A total of 939 different items of medical literature were filed in the three cases, the complexity of the material involving many different specialities of biology and medicine, including neurology, gastroenterology, virology, immunology, molecular biology, toxicology, genetics and epidemiology.<sup>38</sup>

## (ii) The First General Causation Theory

The petitioners advanced a causation theory which had several parts, including three main contentions, viz: (1) that thimerosal-containing vaccines can cause immune dysfunction; (2) that the MMR vaccine can cause autism; and (3) that the MMR vaccine can cause gastrointestinal dysfunction.<sup>39</sup> It was agreed that the Petitioners’ Steering Committee (PSC) would present its general causation evidence concerning the first theory, along with all the evidence specific to the *Cedillo* case.<sup>40</sup> As to each of the general causation theory elements, Special Master Hastings concluded that ‘the evidence was overwhelmingly contrary to the petitioners’ contentions’.<sup>41</sup> Considerable emphasis was placed on the respondent’s expert witnesses, who were ‘far better qualified, far more experienced and far more persuasive than the petitioners’ experts concerning most of the key points’.<sup>42</sup> The numerous medical studies came down strongly against the petitioners’ contentions. Having considered all the evidence, the Special Master found that the petitioners had failed to demonstrate that thimerosal-containing vaccines in general could contribute to causing immune dysfunction or that the MMR vaccine could contribute to causing either autism or gastrointestinal dysfunction.<sup>43</sup>

The petitioners’ general causation theory concerning the causation of autism was contingent on a weakening of the immune system by thimerosal-containing

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<sup>36</sup> *Cedillo v Secretary of Health & Human Services*, 2009 WL 331968 (Fed CI Feb 12, 2009) at \*14.

<sup>37</sup> *ibid* at \*14–15.

<sup>38</sup> *ibid*. For a comprehensive discussion of the early stages of the Omnibus Autism Proceeding prior to the decisions in the test cases being decided, as well as discussion of potential problems in the aftermath of the Proceeding, see, G Shemin, ‘Mercury Rising: The Omnibus Autism Proceeding and What Families Should Know Before Rushing Out of Vaccine Court’ (2008) 58 *American University Law Review* 459.

<sup>39</sup> *Cedillo v Secretary of Health & Human Services*, 2009 WL 331968 (Fed CI Feb 12, 2009) at \*1.

<sup>40</sup> *Cedillo v Secretary of Health & Human Services*, 2009 WL 331968 (Fed CI Feb 12, 2009) at \*10.

Then, over the following months, the PSC would present its case-specific evidence concerning the two additional test cases, viz, *Snyder v Secretary of Health & Human Services*, 01-162V, 2009 WL 332044 (Fed CI Feb 12, 2009) and *Hazlehurst v Secretary of Health & Human Services*, 03-654V, 2009 WL 332306 (Fed CI Feb 12, 2009): *ibid*.

<sup>41</sup> *Cedillo v Secretary of Health & Human Services*, 2009 WL 331968 (Fed CI Feb 12, 2009) at \*1. See, also, *Snyder v Secretary of Health & Human Services*, 01-162V, 2009 WL 332044 (Fed CI Feb 12, 2009) at \*1, Special Master Vowell.

<sup>42</sup> *Cedillo v Secretary of Health & Human Services*, 2009 WL 331968 (Fed CI Feb 12, 2009) at \*1. See also *Snyder v Secretary of Health & Human Services*, 01-162V, 2009 WL 332044 (Fed CI Feb 12, 2009) at \*1, Special Master Vowell (stating that ‘it was abundantly clear that petitioners’ theories of causation were speculative and unpersuasive’); and *Hazlehurst v Secretary of Health & Human Services*, 03-654V, 2009 WL 332306 (Fed CI Feb 12, 2009) at \*13.

<sup>43</sup> *Cedillo v Secretary of Health & Human Services*, 2009 WL 331968 (Fed CI Feb 12, 2009) at \*1. See also *Snyder v Secretary of Health & Human Services*, 01-162V, 2009 WL 332044 (Fed CI Feb 12, 2009) at \*1, \*76, \*104, \*137; *Hazlehurst v Secretary of Health & Human Services*, 03-654V, 2009 WL 332306 (Fed CI Feb 12, 2009) at \*85, \*150, \*171.



vaccines which allowed the measles virus contained in the MMR vaccine to persist within the child's body.<sup>44</sup> However, the determination by the Special Masters in all three cases that the testing for the presence of the measles virus in the intestinal tissue of Cedillo, Snyder and Hazlehurst and other autistic children was *unreliable*<sup>45</sup> was fatal to all three decisions.

The petitioners' general theory concerning the causation of autism was rejected on the basis of nine grounds, viz:

- (1) the general theory depended upon the existence of reliable laboratory test findings of persisting measles virus, but such a reliable test did not exist;<sup>46</sup>
- (2) the available evidence did not demonstrate any substantial likelihood that measles virus persistence in the brain would cause autism;<sup>47</sup>

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<sup>44</sup> *Cedillo v Secretary of Health & Human Services*, 2009 WL 331968 (Fed CI Feb 12, 2009) at \*15; *Snyder v Secretary of Health & Human Services*, 01-162V, 2009 WL 332044 (Fed CI Feb 12, 2009) at \*28; *Hazlehurst v Secretary of Health & Human Services*, 03-654V, 2009 WL 332306 (Fed CI Feb 12, 2009) at \*86. The Special Master in *Hazlehurst* summarised the theory of causation as follows: 'Specifically, petitioners assert that the measles component of the MMR vaccine causes an immune dysfunction that impairs the vaccinee's ability to clear the measles virus. Unable to clear properly ... the measles virus from the body, the vaccinee experiences measles virus persistence which leads to chronic inflammation in the gastrointestinal system and, in turn, chronic inflammation in the brain. Petitioners argue that the inflammation in the brain causes neurological damage that manifests as autism. It is also the position of petitioners that the viral persistence is facilitated by the vaccinee's receipt of thimerosal containing vaccines that suppress the immune system of the vaccinee and impair the immune system's ability to respond properly to the viral presence': *ibid* at \*86.

<sup>45</sup> *Cedillo v Secretary of Health & Human Services*, 2009 WL 331968 (Fed CI Feb 12, 2009) at \*29–59, *aff'd*, 89 Fed CI 158, 171–72 (2009), *aff'd* 617 F 3d 1328, 1345 (Fed Cir 2010); and, further, *Snyder v Secretary of Health & Human Services*, 01-162V, 2009 WL 332044 (Fed CI Feb 12, 2009) at \*116; *Hazlehurst v Secretary of Health & Human Services*, 03-654V, 2009 WL 332306 (Fed CI Feb 12, 2009) at \*150. The studies purported to find the presence of the measles virus in the biological material of autistic children and primarily derived from two sources: the work of Dr Andrew Wakefield of the Royal Free Hospital in London (see, in particular, his article, AJ Wakefield, et al, 'Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children' [retracted] (1998) 351 *Lancet* 637–41), and his colleagues John O'Leary and Orla Sheils at the for profit, non-accredited Unigenetics laboratory in Dublin; and the research of Dr Stephen Walker of Wake Forest University School of Medicine, North Carolina. Dr Wakefield and his colleagues were 'the principle proponents of the hypothesis that the receipt of the MMR vaccine results in the development of autism spectrum disorders and gastrointestinal problems in certain children': *Hazlehurst v Secretary of Health & Human Services*, 03-654V, 2009 WL 332306 (Fed CI Feb 12, 2009) at \*87, \*126. The Special Master found that the work of Dr Wakefield had been largely discredited and that none of the studies indicating the presence of the measles virus in autistic children had been successfully replicated independently of Wakefield or Unigenetics: *ibid* at \*90, 124. The testimony of a government expert, Professor Stephen Bustin (who had also been an expert for the vaccine manufacturers in the UK MMR litigation) helped to discredit the reliability of the testing conducted at Unigenetics: *ibid* at \*129–32. It was held on appeal that this testimony had been properly admitted: *Hazlehurst v Secretary of Health & Human Services* 88 Fed CI 473, 480–83 (2009), *aff'd*, 604 F 3d 1343, 1349–50 (Fed Cir 2010). Shortly before the first test case, *Cedillo*, was due to begin, the Secretary of Health and Human Services was granted permission to obtain from the records of the High Court, copies of expert witness reports of Professors Bustin, Simmonds and Rima, filed by the defendants in the UK MMR/MR Vaccine Litigation, so as to use these documents in the Omnibus Autism Proceedings in the US: *Sayers v Smithkline Beecham Plc, Smith Kline & French Laboratories Ltd, Merck & Co Inc, Sanofi Pasteur MSD Ltd* [2007] EWHC 1346 (QB).

<sup>46</sup> *ibid* at \*67–68.

<sup>47</sup> *ibid* at \*67–69.

- (3) the evidence indicated that the wild measles virus had never been shown to cause autism, which made it quite unlikely that the vaccine strain form of the measles virus could cause autism;<sup>48</sup>
- (4) the petitioners' theory seemed unlikely in the light of several accepted understandings concerning the causation of autism, in particular that there was a very strong genetic component to the causation of autism;<sup>49</sup>
- (5) there were contradictions and inconsistencies in the testimony concerning the appropriate time period between the MMR vaccination and the onset of autism symptoms;<sup>50</sup>
- (6) the testimony of three other experts failed to provide substantial support to the causation theory of the petitioners' expert Dr Kinsbourne;<sup>51</sup>
- (7) the qualifications of the respondent's experts concerning this issue substantially exceeded the qualifications of the petitioners' expert witnesses;<sup>52</sup>
- (8) the epidemiologic evidence consisting of numerous studies by qualified medical researchers around the world<sup>53</sup> added another reason to reject the petitioners' theory that vaccines could contribute to the causation of autism;<sup>54</sup> and

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<sup>48</sup> *ibid* at \*67, \*69–71.

<sup>49</sup> *ibid* at \*67, \* 71–77.

<sup>50</sup> *ibid* at \*67, \*77–79.

<sup>51</sup> *ibid* at \*67, \*79–83.

<sup>52</sup> *ibid* at \*67, \*83–84.

<sup>53</sup> See B Taylor, et al, 'Autism and Measles, Mumps, and Rubella Vaccine: No Epidemiological Evidence for a Causal Association' (1999) 353 *Lancet* 2026–29; F DeStefano, et al, 'Age at First Measles-Mumps-Rubella Vaccination in Children With Autism and School-Matched Control Subjects: A Population-Based Study in Metropolitan Atlanta' (2004) 113 *Pediatrics* 259–66; L Smeeth, et al, 'MMR Vaccination and Pervasive Developmental Disorders: A Case-Control Study' (2004) 364 *Lancet* 963–69; B Taylor, et al, 'Measles, Mumps, and Rubella Vaccination and Bowel Problems or Developmental Regression in Children with Autism: Population Study' (2002) 324 *British Medical Journal* 393–96; CP Farrington, et al, 'MMR and Autism: Further Evidence Against a Causal Association' (2001) 19 *Vaccine* 3632–35; E Fombonne and S Chakrabarti, 'No Evidence for a New Variant of Measles-Mumps-Rubella-Induced Autism' (2001) 108 *Pediatrics* e58; S Dewilde, 'Do Children Who Become Autistic Consult More Often After MMR Vaccination?', (2001) 51 *British Journal of General Practice* 226–27; A Mäkelä, et al, 'Neurologic Disorders After Measles-Mumps-rubella Vaccination' (2002) 110 *Pediatrics* 957–63; H Takahashi, et al, 'An Epidemiological Study on Japanese Autism Concerning Routine Childhood Immunization History' (2003) 56 *Japanese Journal of Infectious Diseases* 114–17; W Chen, et al, 'No Evidence for Links Between Autism, MMR and Measles Virus' (2004) 34 *Psychological Medicine* 543–53; H Honda, et al, 'No Effect of MMR Withdrawal on the Incidence of Autism: A Total Population Study' (2005) 46 *Journal of Child Psychology and Psychiatry* 572–79.

<sup>54</sup> *ibid* at \*67, \*92–93. Special Master Hastings effectively destroyed the sufficiency of the epidemiologic evidence proffered by the petitioners in the following two paragraphs: 'The numerous epidemiologic studies done over the past ten years, when taken together, make it *very unlikely* that the MMR vaccination has played any significant role in the *overall causation* of autism. It is true, as the petitioners argue, that the available epidemiologic studies do not *completely rule out* the possibility that the MMR vaccine might be associated with some small subset of autism, such as regressive autism. However, there are three reasons why the epidemiologic evidence *still* must be said to provide significant evidence *against* the petitioners' general causation theory set forth in this case. First, none of the numerous competent studies *has yielded the slightest bit of evidence in the petitioners' favor*. Second, the failure of so many studies to find any association between MMR vaccine and autism, while not *completely ruling out* a possible causal role with respect to a *subset* of autism, at least *casts considerable doubt* upon the proposition that the MMR vaccine *ever* plays a role

- (9) Two reports of well-qualified experts published by the Institute of Medicine in 2001 and 2004 studied the general MMR/autism causation issue and concluded that the evidence favoured rejection of the proposition that the MMR vaccine could cause autism.<sup>55</sup>

Taken together, all this evidence was irrefutable.

## C. The Second Three Test Cases and the Petitioners' Second Theory

### (i) The Second Three Test Cases

The Petitioners Steering Committee's second causation theory was that thimerosal-containing vaccines alone can cause autism.<sup>56</sup> The same three Special Masters who had been tasked with hearing the first three test cases concerning the first theory of general causation were also tasked with hearing the second three test cases concerning the second theory of general causation advanced by the petitioners.<sup>57</sup> The evidentiary record was described as 'massive',<sup>58</sup> and one which exceeded any evidentiary record in any Program case, with the exception of the record in the first three test cases. During the evidentiary hearings, a total of 26 expert witnesses testified. The amount of medical literature filed into the records of the three cases was a 'staggering' figure of more than 1200 different items.<sup>59</sup> In March 2010, each of the three Special Masters issued a decision in the test case assigned to them, ie respectively in *Mead*,<sup>60</sup> *Dwyer*<sup>61</sup> and *King*.<sup>62</sup> All three Special Masters found that the parents had failed to prove that their children's autism was caused by the thimerosal-containing vaccines that they received.<sup>63</sup>

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in causing any kind of autism, including regressive autism. And, third, five studies provide evidence that is *directly relevant* to the petitioners' "regressive autism only" argument, supplying significant evidence *against* the theory that the MMR vaccine plays a causal role *even* in the subset of autism known as regressive autism.

Accordingly, my conclusion is that the epidemiologic evidence *does* provide yet another strong reason to *reject* the petitioners' general causation theory presented in this case': *ibid* at\* 92–93.

<sup>55</sup> *ibid* at \*68, \*93–94; see Institute of Medicine, *Immunization Safety Review: Measles-Mumps-Rubella Vaccine and Autism* (Washington DC, The National Academies Press, 2001), p 60; Institute of Medicine, *Immunization Safety Review: Vaccines and Autism* (Washington DC, The National Academies Press, 2004) 7, 16, 126, 151–52.

<sup>56</sup> *Mead v Secretary of Health & Human Services*, 03-215V, 2010 WL 892248 (Fed CI March 12, 2010) at \*2.

<sup>57</sup> *Mead v Secretary of Health & Human Services*, 03-215V, 2010 WL 892248 (Fed CI March 12, 2010) at \*4.

<sup>58</sup> *King v Secretary of Health & Human Services*, 03-584V, 2010 WL 892296 (Fed CI March 12, 2010) at \*12.

<sup>59</sup> *ibid*.

<sup>60</sup> *Mead v Secretary of Health & Human Services*, 03-215V, 2010 WL 892248 (Fed CI March 12, 2010).

<sup>61</sup> *Dwyer v Secretary of Health & Human Services*, 03-1202V, 2010 WL 892250 (Fed CI March 12, 2010).

<sup>62</sup> *King v Secretary of Health & Human Services*, 03-584V, 2010 WL 892296 (Fed CI March 12, 2010).

<sup>63</sup> *Mead v Secretary of Health & Human Services*, 03-215V, 2010 WL 892248 (Fed CI March 12, 2010) at \*1, 13, 113; *Dwyer v Secretary of Health & Human Services*, 03-1202V, 2010 WL 892250 (Fed CI March 12, 2010) at \*1–2, 201; *King v Secretary of Health & Human Services*, 03-584V, 2010 WL 892296 (Fed CI March 12, 2010) at \*1, 90–91.

## (ii) The Second General Causation Theory

The petitioners' medical theory contended that 'the thimerosal component of the received childhood vaccines dissociates into organomercurial ethylmercury once in the body'.<sup>64</sup> That ethylmercury 'then courses through the blood stream to diffuse across the blood-brain barrier to reach the brain'.<sup>65</sup> On reaching the brain, 'the ethylmercury is de-ethylated to become inorganic mercury – a form of mercury that is not quickly removed from the brain – and once deposited, provokes a series of detrimental responses that ultimately manifest as autism'.<sup>66</sup> It was found that the underpinnings for the opinions of the petitioners' experts concerning the second theory were 'scientifically flawed', and in the absence of a sound basis for the offered opinions of causation, these opinions '[could not] be credited'.<sup>67</sup> The theory that the thimerosal content of the vaccines contributed to the development of autism was 'scientifically unsupportable'.<sup>68</sup>

Several epidemiological studies<sup>69</sup> were examined and it was found that they showed no association between thimerosal-containing vaccines and the development of autistic spectrum disorders.<sup>70</sup> Reference was made to the evidence given by the

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<sup>64</sup> *Mead v Secretary of Health & Human Services*, 03-215V, 2010 WL 892248 (Fed CI March 12, 2010) at \*106; and further, at \*17.

<sup>65</sup> *ibid.*

<sup>66</sup> *ibid.*

<sup>67</sup> *Mead v Secretary of Health & Human Services*, 03-215V, 2010 WL 892248 (Fed CI March 12, 2010) at \*109, citing *Perreira v Secretary of Health & Human Services* 33 F 3d 1375, 1377 fn 6 (Fed Cir 1994) ('An expert opinion is no better than the soundness of the reasons supporting it').

<sup>68</sup> *Mead v Secretary of Health & Human Services*, 03-215V, 2010 WL 892248 (Fed CI March 12, 2010) at \*113; see, further, *Dwyer v Secretary of Health & Human Services*, 03-1202V, 2010 WL 892250 (Fed CI March 12, 2010) at \*165, 198–99; *King v Secretary of Health & Human Services*, 03-584V, 2010 WL 892296 (Fed CI March 12, 2010) at \*34–35.

<sup>69</sup> See A Hviid, et al, 'Association Between Thimerosal-Containing Vaccine and Autism' (2003) 290 *Journal of American Medical Association* 1763–66; K Madsen, et al, Thimerosal and the Occurrence of Autism: Negative Ecological Evidence From Danish Population-Based Data (2003) 112 *Pediatrics* 604–6; T Verstraeten, et al, 'Safety of Thimerosal-Containing Vaccines: A Two Phased Study of Computerized Health Maintenance Organization Databases' (2003) 112 *Pediatrics* 1039–48; P Stehr-Green, et al, 'Autism and Thimerosal-Containing Vaccines' (2003) 25 *American Journal of Preventative Medicine* 101–6; N Andrews, et al, 'Thimerosal Exposure in Infants and Developmental Disorders: A Retrospective Cohort Study in the United Kingdom Does Not Support a Causal Association' (2004) 114 *Pediatrics* 584–91; H Jick and J Kaye, 'Autism and DPT Vaccination in the United Kingdom' (2004) 350 *New England Journal of Medicine* 2722–23; E Fombonne, et al, 'Pervasive Development Disorders in Montreal, Quebec, Canada: Prevalence and Links with Immunizations' (2006) 118 *Pediatrics* e139–50; R Schechter and J Grether, 'Continuing Increases in Autism Reported to California's Developmental Services System' (2008) 65 *Archives of General Psychiatry* 19–24. Two other studies did not directly address the question of an association between thiomersal and autism, but provided relevant information: (see J Heron and J Golding, 'Thimerosal Exposure in Infants and Developmental Disorders: A Prospective Cohort Study in the United Kingdom Does Not Support a Causal Association' (2004) 114 *Pediatrics* 577–83; and WW Thompson, et al, 'Early Thimerosal Exposure and Neuropsychological Outcomes at 7 to 10 Years' (2007) 357 *New England Journal of Medicine* 1281–92). In the light of the strength of the epidemiological evidence of no association, and given the absence of any direct evidence for a biological mechanism, the Institute of Medicine concluded that the evidence favoured rejection of a causal association between thimerosal-containing vaccines and autism: Institute of Medicine, *Immunization Safety Review: Vaccines and Autism* (Washington DC, The National Academies Press, 2004) 16, 151–52.

<sup>70</sup> *Mead v Secretary of Health & Human Services*, 03-215V, 2010 WL 892248 (Fed CI March 12, 2010) at \*39. See, further, *Dwyer v Secretary of Health & Human Services*, 03-1202V, 2010 WL 892250 (Fed CI March 12, 2010) at \*77 ('In this case, the epidemiological studies furnish powerful evidence refuting a causal association between TCVs [thimerosal-containing vaccines] and ASD'); and

eminent paediatric psychiatrist, Professor Sir Michael Rutter who, having examined the limitations of the epidemiological studies, had concluded that ‘taken as whole, the studies were all “unsupportive of a causal association”’.<sup>71</sup>

## D. Implications of the Test Cases

### (i) Epidemiological Evidence Should be Given Appropriate Weight

Some of the most significant evidence used to reject the general causation theory were the numerous epidemiologic studies performed over the previous 10 years which, when taken together, made it very unlikely that the MMR vaccination played a significant role in the overall causation of autism.<sup>72</sup> Both the *Cedillo* and *King* test cases, determined by Special Master Hastings, clarify the position surrounding the use of such epidemiological evidence supporting a causation-in-fact claim under the National Vaccine Injury Compensation Program (the Program). They reaffirm the settled legal position that while there is no requirement that epidemiological evidence supports a causation-in-fact claim under the Program,<sup>73</sup> in the relatively rare instance in which general causation *has* been the subject of published epidemiological studies, such evidence should be given appropriate weight, along with the other evidence of the record.<sup>74</sup>

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*King v Secretary of Health & Human Services*, 03-584V, 2010 WL 892296 (Fed CI March 12, 2010) at \* 66–67. While the petitioners conceded through their expert, Professor Sander Greenland, that the epidemiologic literature to date had not detected an association of mercury-containing vaccines and autism in general or autistic spectrum disorders, Dr Greenland claimed that the performed epidemiological studies lacked the requisite specificity to detect an association between the receipt of thimerosal-containing vaccines and regressive autism: *Mead v Secretary of Health & Human Services*, 03-215V, 2010 WL 892248 (Fed CI March 12, 2010) at \*41–45. This position presumed that regressive autism was a distinct phenotype of autism. However, the Special Master found that studies of the developmental patterns in children described as having early onset autism and in children described as having regressive autism, militated against a finding that regression in autism constituted a separate phenotype of autistic disorder: *ibid* at \*45,112; and further, *Dwyer v Secretary of Health & Human Services*, 03-1202V, 2010 WL 892250 (Fed CI March 12, 2010) at \*62–63 (petitioners failed to demonstrate the existence of ‘clearly regressive autism’ as a separate phenotype; Dr Greenland’s opinion that the existing epidemiologic studies could not rule out a substantial causal rule for thimerosal-containing vaccines in one form of autism was ‘not relevant or persuasive’); and *King v Secretary of Health & Human Services*, 03-584V, 2010 WL 892296 (Fed CI March 12, 2010) at \*39 70–72. When the results of the epidemiological studies were viewed as a whole, they were found to reach the consistent conclusion that there was no association between thimerosal-containing vaccines and autism: *Mead v Secretary of Health & Human Services*, 03-215V, 2010 WL 892248 (Fed CI March 12, 2010) at \*45; *King v Secretary of Health & Human Services*, 03-584V, 2010 WL 892296 (Fed CI March 12, 2010) at \*75.

<sup>71</sup> *ibid* at \*40.

<sup>72</sup> *Cedillo v Secretary of Health & Human Services*, 2009 WL 331968 (Fed CI Feb 12, 2009) at \*123.

<sup>73</sup> *Capizzano v Secretary of Health & Human Services* 440 F 3d 1317, 1325–26 (Fed Cir 2006). Indeed, causation can be demonstrated under the Programme without any support from medical literature: *Althen v Secretary of Health & Human Services* 418 F 3d 1274, 1281 (Fed Cir 2005).

<sup>74</sup> *Cedillo v Secretary of Health & Human Services*, 2009 WL 331968 (Fed CI Feb 12, 2009) at \*92; *King v Secretary of Health & Human Services*, 03-584V, 2010 WL 892296 (Fed CI March 12, 2010) at \*74. See, further, *Hazlehurst v Secretary of Health & Human Services*, 03-654V, 2009 WL 332306 (Fed CI Feb 12, 2009) at \*39; *Terran v Secretary of Health & Human Services* 195 F 3d 1302, 1315–17 (Fed Cir 1999); *Grant v Secretary of Health & Human Services* 956 F 2d 1144, 1149 (Fed Cir 1992). Epidemiologic evidence should be considered in evaluating scientific theories: *Scott v Secretary of Health & Human Services*, 03-2211V, 2006 WL 2559776 at \*21; *Garcia v Secretary of Health &*



## (ii) Reliability of Expert Testimony

Crucial to the determination of these test cases are the factors that a Special Master is required to consider in evaluating the *reliability* of expert testimony and other scientific evidence relating to causation. Even though the Federal Rules of Evidence do not apply in Program cases,<sup>75</sup> the test cases reaffirm that it is appropriate to use the *Daubert*<sup>76</sup> factors as a tool or framework for conducting the inquiry into the reliability of causation in fact theories.<sup>77</sup> In particular, two of the important factors listed in *Daubert* and utilised by the Special Masters in evaluating these theories<sup>78</sup> were whether the scientific theory had been subject to peer review or publication and also whether the theory or technique enjoyed general acceptance.<sup>79</sup> Such epidemiological evidence, while not dispositive, should be considered in evaluating scientific theories, such as the general causation theory in issue in the test cases.<sup>80</sup>

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*Human Services*, 05-720V, 2008 WL 5068934, at \*3, \*10. The reliance of a Special Master on epidemiologic evidence has been subject to express approval: see, eg, *Moberly v Secretary of Health & Human Services* 85 Fed Cl 571, 596 (2009), aff'd, 592 F 3d 1315, 1325 (Fed Cir 2010); *Estep v Secretary of Health & Human Services* 28 Fed Cl 664, 668 (1993); *Sharpnack v Secretary of Health & Human Services* 27 Fed Cl 457, 459 (1993); *Sumrall v Secretary of Health & Human Services* 23 Cl Ct 1, 8 (1991); *Hennessey v Secretary of Health & Human Services*, 01-190V, 2010 WL 94560, at \*6–7, \*11–13.

<sup>75</sup> 42 USC §300aa-12(d)(2)(B): Vaccine Rules ‘shall include flexible informal studies of admissibility of evidence’.

<sup>76</sup> *Daubert v Merrill Dow Pharmaceuticals, Inc* 509 US 579, 593–94 (1993); and, further, *General Electric Co v Joiner*, 522 US 136, 139, 141, 143, 146 (1997); *Kumho Tire Co v Carmichael*, 526 US 137, 147–49, 152–53 (1999); *Weisgram v Marley Co* 528 US 440, 456–57 (2000); Fed. R. Evidence Rule 702, 28 USCA; Fed. R. Evidence 702 Advisory Committee’s Note (2000 Amendment); see DG Owen, *Products Liability Law*, 2nd edn (St Paul, MN Thomson/West, 2008) § 6.3. For criticism that *Daubert* and its progeny have in some cases hindered the search for justice in product liability law, see, generally, C Cranor, *Toxic Torts: Science, Law, and the Possibility of Justice* (Cambridge University Press, 2007) and, in particular, *ibid* 337, 340–41, 348, 353, 356, 368.

<sup>77</sup> *Cedillo v Secretary of Health & Human Services*, 2009 WL 331968 (Fed Cl Feb 12, 2009) at \*3; aff'd, 89 Fed Cl 158, 182 (2009), aff'd 617 F 3d 1328, 1338–38 (Fed Cir 2010), (applying *Terran v Secretary of Health & Human Services* 195 F 3d 1302, 1316 (Fed Cir 1999)); *Snyder v Secretary of Health & Human Services*, 01-162V, 2009 WL 332044 (Fed Cl Feb 12, 2009) at \*30, \*138, \*194, aff'd 88 Fed Cl 706, 736, 744–45 (2009); *Hazlehurst v Secretary of Health & Human Services*, 03-654V, 2009 WL 332306 (Fed Cl Feb 12, 2009) at \*16–17; aff'd, 88 Fed Cl 473, 483 (2009), aff'd, 604 F 3d 1343, 1353 (Fed Cir 2010); *Mead v Secretary of Health & Human Services* 03-215V, 2010 WL 892248 (Fed Cl March 12, 2010) at \*13–15; *Dwyer v Secretary of Health & Human Services*, 03-1202V, 2010 WL 892250 (Fed Cl March 12, 2010) at \*7, 25–26; *King v Secretary of Health & Human Services*, 03-584V, 2010 WL 892296 (Fed Cl March 12, 2010) at \*3, 73. For further approval of the utilisation of the *Daubert* factors in evaluating the reliability of scientific evidence in cases under the Program, see *Moberly v Secretary of Health & Human Services* 592 F 3d 1315, 1324 (Fed Cir 2010); *Andreu v Secretary of Health & Human Services* 569 F 3d 1367, 1379 (Fed Cir 2009); *Knudsen v Secretary of Health & Human Services* 35 F 3d 543, 548 (Fed Cir 1994); *Perreira v Secretary of Health & Human Services* 33 F 3d 1375, 1377 fn 6 (Fed Cir 1994).

<sup>78</sup> *Cedillo v Secretary of Health & Human Services*, 2009 WL 331968 (Fed Cl Feb 12, 2009) at \*3.

<sup>79</sup> *Daubert v Merrill Dow Pharmaceuticals, Inc* 509 US 579, 593–94 (1993).

<sup>80</sup> *Terran v Secretary of Health & Human Services* 195 F 3d 1302, 1315–17 (Fed Cir 1999); *Grant v Secretary of Health & Human Services* 956 F 2d 1144, 1149 (Fed Cir 1992); *Scott v Secretary of Health & Human Services*, 03-2211V, 2006 WL 2559776 at \*21; *Garcia v Secretary of Health & Human Services*, 05-720V, 2008 WL 5068934, at \*3, \*10; *King v Secretary of Health & Human Services*, 03-584V, 2010 WL 892296 (Fed Cl March 12, 2010) at \*74.



### (iii) The Causation-in-Fact Standard: General and Specific Causation and Temporal Proximity

One of the most interesting aspects of the test cases is their utilisation of the causation-in-fact standard. The cases emphasise the importance of establishing both general and specific causation in vaccine damage cases, as well as the need for temporal proximity between the vaccine and the damage in each case. This legal standard of proof for causation in fact under the Program was elaborated on in the leading case of *Althen v Secretary of Health & Human Services*.<sup>81</sup> There, the Federal Circuit established three factors which had to be satisfied to overcome the burden of proof, viz: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and the injury.<sup>82</sup> In all six test cases in the Omnibus Autism Proceeding, the Special Masters were able to explain how their analyses of the petitioners' contentions on the scientific evidence fitted within the three prongs of the test and how in each case none of the requirements of the three factors were satisfied.<sup>83</sup>

The principal test case of the first general causation theory, *Cedillo*, provides an important explanation of the three prongs of the *Althen* test. The first prong, viz the requirement of a medical theory causally connecting the vaccination and the injury is explained as a *general* causation requirement, ie that the type of vaccination in question *can* cause the type of injury in question. The second prong, a logical sequence of cause and effect showing that the vaccination was the reason for the injury, is explained as a *specific* causation requirement, ie that the particular vaccination received by the specific vaccinee *did* cause the vaccinee's own injury. *Cedillo* affirms the '*can/did* cause' test, as being equivalent to the first two prongs of *Althen*.<sup>84</sup> Applying the available scientific evidence, the Special Master held that the petitioners' arguments fell far short of demonstrating that the MMR vaccination *could* contribute in general to the causation of either autism or chronic gastrointestinal dysfunction, or that the MMR vaccination *did* contribute to the causation of *Cedillo*'s own autism and gastrointestinal symptoms.<sup>85</sup> Moreover, there was no doubt that the *Althen* test required that as an overall matter, a petitioner had to demonstrate that it

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<sup>81</sup> *Althen v Secretary of Health & Human Services* 418 F 3d 1274 (Fed Cir 2005).

<sup>82</sup> *ibid* 1278.

<sup>83</sup> *Cedillo v Secretary of Health & Human Services*, 2009 WL 331968 (Fed CI Feb 12, 2009) at \*132–33; *aff'd*, 89 Fed CI 158, 182–83 (2009); For discussion of the application of the *Althen* test in the other two test cases of the first general causation theory, see *Snyder v Secretary of Health & Human Services*, 01-162V, 2009 WL 332044 (Fed CI Feb 12, 2009) at \*29, \*192–98, *aff'd* 88 Fed CI 706, 745–46 (2009) and *Hazlehurst v Secretary of Health & Human Services*, 03-654V, 2009 WL 332306 (Fed CI Feb 12, 2009) at \*15–19, \*83–86. For discussion of the application of the *Althen* test in the three test cases of the second general causation theory, see *Mead v Secretary of Health & Human Services*, 03-215V, 2010 WL 892248 (Fed CI March 12, 2010) at \*15–16, 106–13; *Dwyer v Secretary of Health & Human Services*, 03-1202V, 2010 WL 892250 (Fed CI March 12, 2010) at \*23–24, 196–201; *King v Secretary of Health & Human Services*, 03-584V, 2010 WL 892296 (Fed CI March 12, 2010) at \*87–89.

<sup>84</sup> *Cedillo v Secretary of Health & Human Services*, 2009 WL 331968 (Fed CI Feb 12, 2009) at \*131, affirming *Pafford v Secretary of Health & Human Services* 451 F 3d 1352, 1355–56 (Fed Cir 2006); and, further, in respect of the second general causation theory, *Dwyer v Secretary of Health & Human Services*, 03-1202V, 2010 WL 892250 (Fed CI March 12, 2010) at \*197; *King v Secretary of Health & Human Services*, 03-584V, 2010 WL 892296 (Fed CI March 12, 2010) at \*87.

<sup>85</sup> *Cedillo v Secretary of Health & Human Services*, 2009 WL 331968 (Fed CI Feb 12, 2009) at \*132; *aff'd*, 89 Fed CI 158, 182–83 (2009); *aff'd* 617 F 3d 1328, 1338 (Fed Cir 2010).

was more probable than not that the particular vaccine was a substantial contributing factor in causing the particular injury in question.<sup>86</sup> This was clear from the ‘preponderance of evidence’ standard in the Vaccine Act.<sup>87</sup> Regardless of the precise meanings of *Althen*, the overall evidence fell far short of demonstrating that it was ‘more probable than not’ that the MMR vaccine contributed to the causation of either Cedillo’s autism or gastrointestinal symptoms.<sup>88</sup> The petitioners also failed to satisfy the third element of *Althen*, viz the need to show a ‘proximate temporal relationship between vaccination and injury’.<sup>89</sup> They were unable to establish that the first symptom of autism and/or the first symptoms of the chronic gastrointestinal problems occurred within a time-frame consistent with causation by the MMR vaccination in question.<sup>90</sup>

#### (iv) Looking Beyond the Epidemiology: The Overall Evidence

A strength of these Omnibus Autism Proceeding test cases is that in determining whether the petitioners have demonstrated causation by a preponderance of evidence, the Special Masters have looked *beyond* the epidemiologic evidence to determine whether the *overall evidence* – ie medical opinion and circumstantial evidence and other evidence considered as a whole – tipped the balance even slightly in favour of a causation showing.<sup>91</sup> Ultimately, in each case, the overall weight of the evidence was overwhelmingly contrary to the petitioners’ causation theories. In respect of general causation, the evidence advanced by the petitioners had fallen far short of demonstrating a causal link.<sup>92</sup>

#### (v) On the Side of Science

Thus we can conclude that in these important test cases, the Special Masters have come down clearly on the side of science, and in doing so have considered the evidence overall. Indeed, one master, Special Master George Hastings in *Cedillo*

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<sup>86</sup> *ibid.*

<sup>87</sup> *ibid.*, citing § 300aa-13(a)(I)(A).

<sup>88</sup> *Cedillo v Secretary of Health & Human Services*, 2009 WL 331968 (Fed CI Feb 12, 2009) at \*132; *aff’d*, 89 Fed CI 158, 182–83 (2009); and, further, in respect of the second general causation theory, *King v Secretary of Health & Human Services*, 03-584V, 2010 WL 892296 (Fed CI March 12, 2010) at \*88.

<sup>89</sup> *Althen v Secretary of Health & Human Services* 418 F 3d 1274, 1278 (Fed Cir 2005).

<sup>90</sup> *Cedillo v Secretary of Health & Human Services*, 2009 WL 331968 (Fed CI Feb 12, 2009) at \*132–33, *aff’d*, 89 Fed CI 158, 182–83 (2009); *Pafford v Secretary of Health & Human Services* 451 F 3d 1352, 1358 (Fed Cir 2006) (need for evidence demonstrating petitioner’s injury within medically accepted time-frame). cf the view that the OAP reveals the competing policy tensions between compensating injured petitioners and upholding the public confidence in vaccines and their use, and that these unresolved policy conflicts have revealed a tension that has fallen on the shoulders of the Special Masters presiding over the OAP, which is illustrated by *Cedillo*: LA Binski, ‘Balancing Policy Tensions of the Vaccine Act In Light of the Omnibus Autism Proceeding: Are Petitioners Getting a Fair Shot at Compensation?’ (2011) 39 *Hofstra Law Review* 683, 688, 705–10, 715, 720. Binski submits that more guidance needs to be given to Special Masters as to how to strike the balance between these competing concerns in causation-in-fact cases: *ibid* 716–20.

<sup>91</sup> In determining if a petitioner is entitled to compensation, the Special Master is not bound by any diagnosis, conclusion, judgment, test result, report, or summary, and in evaluating the weight to be afforded to such matters, ‘shall consider the *entire* record’: 42 USC § 300aa-13(b)(1) (emphasis added).

<sup>92</sup> *Cedillo v Secretary of Health & Human Services*, 2009 WL 331968 (Fed CI Feb 12, 2009) at \*134–35; and, further, in respect of the second general causal theory, *King v Secretary of Health & Human Services*, 03-584V, 2010 WL 892296 (Fed CI March 12, 2010) at \*91.

severely criticised those physicians who are supporting a link between MMR and autism. He stated that: ‘Unfortunately, the Cedillos have been misled by physicians who are guilty of gross medical misjudgment’.<sup>93</sup> All of the Special Masters concluded that the petitioners had failed to demonstrate that the vaccinations played any role in causing autism.

## V. A FRENCH COMPARISON: THE LIBERAL FRENCH APPROACH TO HEPATITIS B VACCINE AND DEMYELINATING DISEASES USING PRESUMPTIONS OF CAUSATION

### A French Comparison

In contrast to the US, a much more liberal approach to causation appeared to be established in France by the Cour de cassation, principally in the context of claims for compensation for demyelinating diseases, allegedly caused or exacerbated by vaccinations against hepatitis B.

In 2003, the Cour de cassation held that causation between the hepatitis B vaccination and multiple sclerosis could not be established given the absence of scientific certainty on the possible link between the vaccine and the disease.<sup>94</sup> However, the Cour de cassation shifted its position on 22 May 2008, when it acknowledged in a series of five cases concerning hepatitis B in which it was alleged to have caused neurological disorders,<sup>95</sup> and one case concerning two medications that were alleged to have caused Lyell’s syndrome,<sup>96</sup> that a causal link could be established by the presence of ‘serious, precise and concurrent’ presumptions of causation. Such presumptions had to be supported by specific causation-related data submitted by each specific claimant on a case-by-case basis relating to the claimant’s medical history, but not through generalised statistical or probabilistic studies. As a result, despite the absence of any scientific and statistical data showing a causal link between hepatitis B vaccine and multiple sclerosis or other neurological illnesses, the Cour de cassation quashed two<sup>97</sup> out of five judgments concerning the hepatitis C vaccine which had previously dismissed claims for compensation. The decisions were quashed on the grounds that the appellate courts had followed ‘a probabilistic

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<sup>93</sup> *Cedillo v Secretary of Health & Human Services*, 2009 WL 331968 (Fed CI Feb 12, 2009) at \*135; and, further, *Dwyer v Secretary of Health & Human Services*, 03-1202V, 2010 WL 892250 (Fed CI March 12, 2010) at \*201 (‘Unfortunately the Dwyers (and uncounted other parents of children with ASD) have relied upon practitioners who peddled hope, not opinions grounded in science and medicine’). It has been predicted that the plaintiffs’ experts, while singled out for their lack of expertise and personal integrity, will continue to testify in future trials, ‘charging handsomely for their services’: PA Offit, *Deadly Choices: How the Anti-Vaccine Movement Threatens Us All* (New York, Basic Books, 2011) 102.

<sup>94</sup> Cass civ 1, 23 September 2003, n° 01-13063, n° 01-13064. See, further, J-S Borghetti, ‘Litigation on Hepatitis B Vaccination and Demyelinating Diseases in France: Breaking Through Scientific Uncertainty?’ (2012) (on file with author). I am grateful to Professor Jean-Sébastien Borghetti, Professor à l’université Panthéon-Assas (Paris II) for a copy of this paper.

<sup>95</sup> Cass Civ 1, 22 May 2008, 5 judgments, n° 05-20.317, n° 06-14.952, n° 05-10.593, n° 06-10.967, n° 06-18.848, I am grateful to Cécile Derycke and Agnès Roman-Amat, Hogan Lovells, Paris, for the provision of copies of several of the French cases utilised in this paper.

<sup>96</sup> Cass Civ 1, 22 May 2008, n° 07-17.200.

<sup>97</sup> Cass Civ 1, 22 May 2008, 2 judgments, n° 06-10.967 and n° 05-20.317.

approach based exclusively on the lack of scientific and statistical link between vaccination and the development of the disease<sup>98</sup> without investigating the specific causation-related data submitted by each claimant and whether this constituted serious, precise and concurrent presumptions of causation. In one appellate judgment, the court had relied on general studies and statistics to determine that there was no causal link between hepatitis B and multiple sclerosis. Accordingly, a claim against a pharmaceutical producer could not be rejected on the sole basis of the absence of any scientific and statistical data showing a causal link between a medicinal product and an illness. This decision to allow the claimants to prove a causal link on the basis of serious, precise and concordant presumptions of causation was confirmed by the Cour de cassation in a judgment of 25 June 2009, where it observed that lower judges cannot require an ‘unquestionable scientific proof’.<sup>99</sup>

This led to considerable concern from the pharmaceutical industry, since the existence of a causal link could no longer be excluded on the basis of an absence of general statistical evidence of a causal link between drug and damage. The industry became worried that this position had opened the door to compensation for the alleged side-effects of medicinal products generally, especially when the Cour de cassation’s position conflicted with legal certainty and fairness in the absence of conclusive epidemiology. It also appeared unclear in what circumstances trial judges would be able to demonstrate the necessary presumption of causation, in cases where there was an absence of scientific evidence of general causation.<sup>100</sup>

The opportunity to confirm what type of facts could potentially give rise to serious, precise and concurrent presumptions quickly arose with the judgment of the Cour de cassation of 9 July 2009.<sup>101</sup> In an extremely controversial judgment, the court went beyond its previous decisions of 22 May 2008 and 25 June 2009, and upheld a judgment by the Court of Appeal of Lyon, granting a patient’s claim against the manufacturer of the hepatitis B vaccine, by finding that causation had been proven even in the absence of general causation, but where such a causal link could not be excluded. The Court of Appeal of Lyon had utilised two factual criteria to establish a presumption of a causal link between the vaccination and the development of multiple sclerosis, viz (1), a temporal proximity between the vaccine injection and the development of the illness; and (2) the absence of other personal risk factors. The Cour de cassation held that while scientific evidence had failed to establish a statistically significant increase in relative risk of multiple sclerosis following vaccination against hepatitis B, nevertheless it could not exclude such a possible link, and there existed proximity between the injection and the development of the disease and an absence of other individual risk factors, such facts could constitute serious precise and concurrent presumptions. From this, a causal link would be inferred between the vaccine and the damage.<sup>102</sup> It is strongly suspected that the purpose of the Cour de cassation’s judgment was to adopt the same position as the Conseil d’État in

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<sup>98</sup> J-S Borghetti, ‘Litigation on Hepatitis B Vaccination and Demyelinating Diseases in France: Breaking Through Scientific Uncertainty?’ (lecture, University of Girona, 15 March 2012).

<sup>99</sup> Cass civ 1, 25 June 2009, n° 08-12781.

<sup>100</sup> C Derycke and A Roman-Amat, ‘Law against science: French Civil Supreme Court opens the door to compensation in product liability cases involving the hepatitis B vaccine’ (June 2008) *Lovells’ European Product Liability Review* 14, 17–18.

<sup>101</sup> Cass civ 1, 9 July 2009, n° 08-11.073; P Brun and O Gout, *Recueil Dalloz* 2010, p 49, 2.

<sup>102</sup> Cass civ 1, 9 July 2009, n° 08-11.073.

actions brought by individuals subject to compulsory vaccination to prevent hepatitis B against the state or other employers.<sup>103</sup>

However, certain French Courts of Appeal have resisted this controversial approach adopted by the Cour de cassation and have continued to refuse to hold manufacturers liable where there is an absence of scientific evidence of general causation.<sup>104</sup> In particular, the Paris Court of Appeal stressed the need to base the decisions on specific personal data of the claimant, whilst at the same time reaffirming the absence of any scientific consensus between hepatitis B vaccine and neurological disorders, the fact that the aetiology is unknown and that multiple sclerosis can be caused by various genetic factors.<sup>105</sup> Moreover, in its judgment of 19 June 2009, the Paris Court of Appeal held that temporal proximity and the absence of personal risk factors did not constitute serious, precise and concurrent presumptions.<sup>106</sup> This position was upheld by the Cour de cassation in its decisions of 24 September 2009, and 25 November 2010.<sup>107</sup> Accordingly, the Cour de cassation appeared to be retreating somewhat from its position on 9 July 2009. Unfortunately, a recent decision of the Cour de cassation<sup>108</sup> suggests that it has performed yet another reversal in upholding the Court of Appeal of Versailles's decision<sup>109</sup> that temporal proximity between the hepatitis B vaccination and the appearance of the demyelinating disease, in the absence of any other known cause for the disease, allowed a presumption that the vaccine had caused the claimant's injury. However, it also ruled, in overturning the decision of the Court of Appeal, that it should have checked if the elements, on the basis of which causation had been presumed, did not also allow a presumption that the vaccine was defective. It therefore suggests that the elements that allow for a presumption of causation may also allow for a presumption of defectiveness. Professor Borghetti has noted that this form of 'intuitive' reasoning

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<sup>103</sup> CE, n° 267635, 9 March 2007. See further, D Fairgrieve and F G'sell-Macrez, 'Causation in French Law: Pragmatism and Policy' in R Goldberg (ed), *Perspectives on Causation* (Oxford, Hart Publishing, 2011) 127; C Derycke and A Roman-Amat, 'The adverse side effects of the French Supreme Court's judgments in relation to the Hepatitis B vaccine' (September 2009) *Lovells' European Product Liability Review* 13, 14.

<sup>104</sup> Cour d'Appel de Paris, n° 04/19067, n° 04/19068, 9 January 2009, Cour d'Appel de Paris, n° 06/13741, 19 June 2009 (upheld by Cour de cassation: Civ 1, n° 09-16.556, 25 November 2010). See also, Cour d'Appel de Bourges, 22 January 2009, n° 07/01489,

<sup>105</sup> Cour d'Appel de Paris, 9 January 2009, RG n° 08/1407, 6; RG n° 04/19067, 8.

<sup>106</sup> Cour d'Appel de Paris, n° 06/13741, 19 June 2009 (upheld by Cour de cassation: Civ 1, n° 09-16.556, 25 November 2010).

<sup>107</sup> Cass civ 1, 24 September 2009, n° 08-16.097, (evidence of claimant (seven month period between vaccination and outbreak of multiple sclerosis, and fact that claimant presented no personal or family history in relation to multiple sclerosis), did not constitute serious, precise and concurrent presumptions of a causal link); Cass civ 1, 25 November 2010 n° 09-16.556 (refusal to establish causation in the absence of scientific consensus in favour of a causal link between the hepatitis B vaccine and multiple sclerosis, despite the existence of proximity between the vaccine injection and the disease (two weeks) and an absence of other individual risk factors. Such evidence, without a scientific consensus in favour of causation, was insufficient to constitute serious, precise and concurrent presumptions). See also the decision of the Cour de cassation prior to its judgment of 9 July 2009: Cass civ 1, 22 January 2009, n° 07-16.449, which confirmed that appellate courts could dismiss patient claims concerning the hepatitis B vaccine, provided that they assess with care not only general causation, but also specific causation, and are able to conclude that the factual evidence submitted to them does not amount to serious, precise and concurrent presumptions of causation; C Derycke and A Roman-Amat, 'The judge and science: a new episode in the hepatitis B vaccine saga' (March 2009) *Lovells' European Product Liability Review* Issue 34, 21, 22.

<sup>108</sup> Cass civ 1, 26 September 2012, n° 11-17.738.

<sup>109</sup> Cour d'appel de Versailles, 10 February 2011.

is unsupported by scientific evidence,<sup>110</sup> and as Fairgrieve and G'Sell-Macrez observe, the 'constant reference to "serious precise and concurrent presumptions" seems somehow to prevent French courts from adopting probabilistic reasoning regarding causation'.<sup>111</sup> It seems that lower French law courts are free to follow their own approaches to the potential link between hepatitis B vaccinations and demyelinating diseases. While a majority of lower courts, including the Paris Court of Appeal, consider that the current state of scientific uncertainty does not permit causation to be presumed on the facts of the case, irrespective of the temporal proximity between the hepatitis B vaccination and the appearance of the demyelinating disease, in a minority of cases the appellate courts are prepared to recognise such a presumption. Unfortunately, this recent decision of the Cour de cassation follows that minority view. However, in its most recent decision, the Cour de cassation, while upholding the approach of assessing all elements at hand when considering a product's defectiveness and the existence of a causal link, has now also held that demonstration of 'imputability' (i.e. general causation between a product and a disease) must be met as a prerequisite prior to the demonstration of damage, defect and causal link.<sup>112</sup> It appears that the aim of this approach is to prevent a complete disconnection between causation in science and law, but it will also result in an increase in the claimant's burden of proof.<sup>113</sup> The inconsistency of these decisions has been unhelpful in generating uncertainty for both claimant and defendant. However, it is submitted that, without scientific evidence of general causation, there should be no question of overcoming the burden of proof of causation in such cases. The Cour de cassation would be wise to study the factors required to overcome that burden as established in the National Vaccine Injury Compensation Program.<sup>114</sup> While the current decisions of the French courts appear to accept prongs two and three of the *Althen*<sup>115</sup> test, viz (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and the injury, the uncertainty seems to stem from whether there should be an acceptance of prong (1), ie a medical theory causally connecting the vaccination and the injury, which is a general causation requirement that the type of vaccine can cause the type of injury in question.<sup>116</sup>

Were the French courts to adopt an *Althen* type approach, which gives primacy to the general causation issue, this would help create more consistency in its decisions, in line with the Cour de cassation's objective laid down in its Annual Report for 2008 to harmonise case law on the hepatitis B vaccine.<sup>117</sup>

<sup>110</sup> J-S Borghetti, 'Qu'est-ce qu'un vaccin défectueux?', *Recueil Dalloz* 2012 2853.

<sup>111</sup> D Fairgrieve and F G'Sell-Macrez, 'Causation in French Law: Pragmatism and Policy' in R Goldberg (ed), *Perspectives on Causation* (Oxford, Hart Publishing, 2011) 127.

<sup>112</sup> Cass civ 1, 29 May 2013, n° 12-20.9033.

<sup>113</sup> I am grateful to Dr Duncan Fairgrieve of British Institute of International Law for sight of an unpublished commentary on this case.

<sup>114</sup> See *Althen v Secretary of Health & Human Services* 418 F 3d 1274, 1278 (Fed Cir 2005), above, 3.(v)(c).

<sup>115</sup> *ibid.*

<sup>116</sup> *Cedillo v Secretary of Health & Human Services*, 2009 WL 331968 (Fed CI Feb 12, 2009) at 131, affirming *Pafford v Secretary of Health & Human Services* 451 F 3d 1352, 1355–56 (Fed Cir 2006); and, further, in respect of the second general causation theory, *Dwyer v Secretary of Health & Human Services*, 03-1202V, 2010 WL 892250 (Fed CI March 12, 2010) at \*197; *King v Secretary of Health & Human Services*, 03-584V, 2010 WL 892296 (Fed CI March 12, 2010) at \*87.

<sup>117</sup> See:

[www.courdecassation.fr/publications\\_cour\\_26/rapport\\_annuel\\_36/rapport\\_2008\\_2903/quatrieme\\_parti](http://www.courdecassation.fr/publications_cour_26/rapport_annuel_36/rapport_2008_2903/quatrieme_parti)



## VI. MMR AND THE GENERAL MEDICAL COUNCIL

### A. The Professional Conduct Hearing

While the test cases have come to their conclusion, the position in the UK shifted to issues of professional misconduct on behalf of Dr Wakefield, and two other doctors who were co-authors on the *Lancet* paper, viz Professor Walker-Smith and Professor (formerly Dr) Murch. These three doctors were referred to the General Medical Council, the body in the UK which is charged with the role of protecting, promoting and maintaining the health and safety of the public by ensuring proper standards in the practice of medicine.<sup>118</sup>

After a hearing lasting 148 days which took over two and a half years to complete, the longest in the history of the GMC, Wakefield was found guilty of dishonesty and irresponsibility by the GMC. In particular, they found that: he had carried out research on the children in breach of Research and Ethics Committee approval;<sup>119</sup> he had subjected several children to intrusive procedures such as lumbar-puncture and colonoscopy that were not clinically indicated;<sup>120</sup> he had intentionally misled the Legal Aid Board by failing to disclose that certain funding subsequently provided by them was not required; he had caused or permitted public funds supplied by the Legal Aid Board to be used for purposes other than those for which it was needed; in respect of conflict of interests, he had failed to disclose to the Editor of the *Lancet* his involvement in the MMR Litigation and that the study had received funding from the Legal Aid Board; and that he had filed a patent application for a new vaccine for the elimination of the MMR and measles virus and for the treatment of inflammatory bowel disease.<sup>121</sup> He also unethically caused blood to be taken from a group of children for research purposes at his son's birthday party.<sup>122</sup> In all these circumstances, and taking into account the standard that might be expected of a doctor practising in the same field of medicine in similar circumstances, the Panel concluded that Wakefield's misconduct not only collectively amounted to serious professional misconduct, but also, when considered individually, constituted multiple separate instances of serious professional misconduct.<sup>123</sup> The Panel concluded that Dr Wakefield's shortcomings and the aggravating factors in this case<sup>124</sup> could not be

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<sup>118</sup> Medical Act 1983, s 1. See, generally, M O'Rourke and J Holl-Allen, 'Regulating Health Care Professionals' in A Grubb, J McHale and J Lang (eds), *Principles of Medical Law*, 3rd edn (Oxford, University Press, 2010).

<sup>119</sup> General Medical Council, Fitness to Practise Panel Hearing, 28 January 2010, pp 7–11.

<sup>120</sup> *ibid* 11–42.

<sup>121</sup> *ibid* 49–50.

<sup>122</sup> *ibid* 54–55.

<sup>123</sup> Dr Andrew Jeremy Wakefield, Determination on Serious Professional Misconduct (SPM) and sanction, 24 May 2010, p 7.

<sup>124</sup> Including 'the wide-ranging transgressions relating to every aspect of his research; his disregard for the clinical interests of vulnerable patients; his failure to heed the warnings he received in relation to the potential conflicts of interest associated with the Legal Aid Board funding; his failure to disclose [his] patent; his dishonesty in relation to the drafting of the *Lancet* paper; and his subsequent representations about it, all played out against a background of research involving such major health implications': *ibid* 8.

addressed by any condition on his registration. Accordingly, it determined that his name should be erased from the medical register, concluding that this was

the only sanction that [was] appropriate to protect patients and [was] in the wider public interest, including the maintenance of public trust and confidence in the profession and [was] proportionate to the serious and wide-ranging findings made against him.<sup>125</sup>

The Panel also concluded that the only appropriate sanction against Professor Walker-Smith was erasure from the medical register.<sup>126</sup> However, while the Panel concluded that Professor Murch had demonstrated errors of judgement, he had acted in good faith, and any professional misconduct on his part could not reach the threshold of serious professional misconduct.<sup>127</sup>

## B. Consequences of the Professional Conduct Hearing

On 6 February 2010, about a week after the findings of fact made against Wakefield and his colleagues, and 12 years after its original publication, the Editors of the *Lancet* finally retracted the 1998 *Lancet* paper. It has been submitted that this should not have taken so long and that until the article's retraction, both Wakefield and claimants could continue to argue that their position was supported in a peer-reviewed journal, albeit an article which had not received general acceptance. Part of the problem here – as any respected epidemiologist will tell us – is that no study can entirely rule out the possibility of a link between MMR and autism. But under the burden of proof in law, it was the claimants who were required to show such a link; there was no burden on the defendants to show that there was none. It is clear that they decisively failed in the United States, and that there was no prospect of them succeeding in the UK.

By the time of its retraction few could deny that Wakefield's *Lancet* paper was fatally flawed, both scientifically and ethically.<sup>128</sup> However, to compound matters, even more disturbing news was to emerge. In early 2011, a series of articles in the British Medical Journal claimed that the 1998 *Lancet* paper was fraudulent on the basis that in not one of the 12 cases could the medical records be fully reconciled with what was published in the descriptions, diagnoses or histories in the journal.<sup>129</sup>

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<sup>125</sup> *ibid* 9.

<sup>126</sup> Professor John Angus Walker-Smith, Determination on Serious Professional Misconduct (SPM) and sanction, 24 May 2010, p 9. This was due to Professor Walker-Smith's 'extensive failures in relation to the clinical care of potentially vulnerable children, his non-compliance with ethical research requirements, and the irresponsible and misleading reporting of research findings potentially having such major implications for public health': *ibid*.

<sup>127</sup> Professor (formerly Dr) Simon Harry Murch, Determination on Serious Professional Misconduct (SPM) and sanction, 24 May 2010, p 7.

<sup>128</sup> F Godlee, J Smith and H Marcovitch, Editorial, 'Wakefield's article linking MMR vaccine and autism was fraudulent' (2011) 342 *British Medical Journal* 64, 65.

<sup>129</sup> B Deer, 'How the Case Against the MMR Vaccine Was Fixed' (2011) 342 *British Medical Journal* 77; B Deer, 'How the Vaccine Crisis was Meant to Make Money' (2011) 342 *British Medical Journal* 136; B Deer, 'The Lancet's Two Days to Bury Bad News' (2011) 342 *British Medical Journal* 200; F. Godlee, J. Smith and H Marcovitch, Editorial, 'Wakefield's article linking MMR vaccine and autism was fraudulent' (2011) 342 *British Medical Journal* 64, 65.

## VII. CONCLUSION

The MMR litigation has shown the incalculable damage that can be caused by one peer reviewed article in a prestigious scientific journal. But for this article, the ensuing publicity in the UK and US would never have transpired. It was this article which fuelled the publicity, which in turn generated the law suits on both sides of the Atlantic. More importantly, it can be argued, it resulted in considerable damage to public health. While vaccination rates in the UK have recovered slightly, they remain below the 95 per cent level recommended by the World Health Organisation to ensure herd immunity.<sup>130</sup> The other damage in the UK was that since the MMR Litigation, the Legal Services Commission became reluctant to fund other multi-party actions in respect of medicinal products that claimants alleged had caused harm.<sup>131</sup>

While there was considerable justification for withdrawal of public funding in the UK, there are some positives that have emerged from the test cases in the US Omnibus Autism Proceeding. Indeed, it is arguable that the US experience in the test cases in autism is in many ways a paradigm of how to address such controversial issues. Unburdened by the emotions of a jury and the usual restrictions imposed by the Federal Rules of Evidence, a single trier of fact has been able to look at all the available evidence and come to a reasoned decision. In these autism test cases, issues of general and specific causation have been addressed and factors personal to the individual children have been taken into account. While the *Daubert* factors have been utilised, they have not prevented evidence being made admissible in these proceedings through an overly strenuous evidentiary threshold. They have been relevant to the assessment of weight at the *adjudication* stage, which has allowed the evidence as a whole to ventilate in the proceedings. It suggests that this more flexible approach to scientific evidence, albeit with high standards at the adjudication stage, is welcome and may counter some of the criticisms<sup>132</sup> of *Daubert* that it has in some cases hindered the search for justice in product liability law. No doubt the most radical approach would be to build on the template of the National Vaccine Injury Compensation Program, and extend it to one involving all prescription drugs generally. This is unlikely to take place in the short term. But what should be possible is a greater flexibility in the use the gatekeeping role for scientific evidence in these types of cases.

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<sup>130</sup> F Godlee, J Smith and H Marcovitch, Editorial, 'Wakefield's article linking MMR vaccine and autism was fraudulent' (2011) 342 *British Medical Journal* 64, 65; see, further, Editorial, 'Junk Science: The Welsh measles epidemic is the price of attacking medical evidence', *The Times*, 16 April 2013, [www.thetimes.co.uk/tto/opinion/leaders/article3740134.ece](http://www.thetimes.co.uk/tto/opinion/leaders/article3740134.ece), accessed 22 April 2013 (discussing a recent measles epidemic that broke out in Wales, and blaming the fall in MMR vaccinations on Wakefield's 1998 *Lancet* paper and on 'credulous commentators who elected to ventriloquise his sensationalist campaign').

<sup>131</sup> This has been seen with the recent withdrawal of funding for the multi-party action claim against the manufacturers of the anti-convulsant medicinal product Epilim, which 80 families had claimed had caused spina bifida, heart damage, learning difficulties, cleft palate and deformities of the hands and feet: see Legal Services Commission, Press Release, 'LSC statement on FACS-Epilim funding', 28 January 2011, available at: [www.legalservices.gov.uk/aboutus/11556\\_12406.asp?page=1](http://www.legalservices.gov.uk/aboutus/11556_12406.asp?page=1). Personal injury claims against pharmaceutical companies will no longer be eligible for legal aid in England and Wales, although they will continue to be eligible in Scotland. See chapter 1 of this volume.

<sup>132</sup> See, for instance, RL Cupp Jr, 'Believing in Products Liability: Reflections on *Daubert*, Doctrinal Evolution and David Owen's *Products Liability Law*' (2006) 40 *University of California, Davis, Law Review* 511, 528–30; and, generally, C Cranor, *Toxic Torts: Science, Law, and the Possibility of Justice* (CUP, 2007).

In France, a liberal approach to causation appeared to be established in France by the Cour de cassation, principally in the context of claims for compensation for demyelinating diseases, allegedly caused or exacerbated by vaccinations against hepatitis B. The Cour de cassation has acknowledged that causal link can be established by the presence of serious, precise and concurrent presumptions of causation. However, the inconsistency of the decisions has been unhelpful in generating uncertainty for both claimant and defendant. It is submitted that, without scientific evidence of general causation, there should be no question of overcoming the burden of proof of causation in such cases. The Cour de cassation would be wise to study the factors required to overcome that burden as established in the National Vaccine Injury Compensation Program, as adumbrated in the *Althen* case, and utilised by the OAP test cases, which, it is submitted, generate more clarity and consistency in approach.

There are also lessons to be learned from the outcome of the General Medical Council hearing. In particular, co-authors of scientific papers will require to verify the source data of studies in a more thorough manner than they have done previously.<sup>133</sup> Such researchers will need to remember that they have a duty to disclose not only actual conflicts of interest, but also perceived conflicts.<sup>134</sup> Research Ethics Committees will be required to establish mechanisms to determine that what was done in a study was actually permitted; they must also be required to work to an effective governance procedure that can impose sanctions when an eventual publication proves that unpermitted acts have taken place.<sup>135</sup>

Another important lesson lies with the role of the media in its reporting of the MMR vaccine scare. They repeatedly reported the concerns of Wakefield, without giving methodological details of the research, whilst ignoring the epidemiological evidence showing no link between MMR and autism.<sup>136</sup> It is important that in future the media recognise the importance of peer-reviewed scientific evidence in such cases, and report it impartially.

However, the principal lesson to be learned from the MMR litigation lies with the wider scientific community. In exercising its freedom to sanction, conduct and publish scientific research, the scientific community as a whole must always exercise eternal vigilance against scientific fraud and misconduct. It is only in these circumstances that good science will have the necessary confidence of the public and the legal system that engages with it.

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<sup>133</sup> F Godlee, J Smith and H Marcovitch, Editorial, 'Wakefield's article linking MMR vaccine and autism was fraudulent' (2011) 342 *British Medical Journal* 64, 65.

<sup>134</sup> Professor Sir Michael Rutter, General Medical Council, Fitness to Practise Panel (Misconduct), Day 37, 1 October 2007, Transcript, 37–55D. This was the position in 1996 as well as now: *ibid.*

<sup>135</sup> *ibid.*

<sup>136</sup> B Goldacre, 'Expert view: The media are equally guilty over the MMR vaccine scare', *The Guardian*, 28 January 2010, available at: [www.guardian.co.uk/science/2010/jan/28/mmr-vaccine-ben-goldacre/print](http://www.guardian.co.uk/science/2010/jan/28/mmr-vaccine-ben-goldacre/print). Professor David Salisbury, Director of Immunisation at the Department of Health, has argued that unlike the US, which has three newspapers that cross the country, the UK has at least 15 national newspapers competing for coverage of a smaller population, which 'leads to more histrionic, more aggressive reporting to seize the audience': PA Offit, *Deadly Choices: How the Anti-Vaccine Movement Threatens Us All* (New York, Basic Books, 2011) 92.